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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/628,090	07/25/2003	Richard Eustis Fulton III	032,290-066	4618

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EXAMINER	
SZMAL, BRIAN SCOTT	
ART UNIT	**PAPER NUMBER**
3736	

DATE MAILED: 12/21/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/628,090	FULTON ET AL.	
	Examiner	Art Unit	
	Brian Szmal	3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-32 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-32 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 7-25-03.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Information Disclosure Statement

1. The information disclosure statement filed July 25, 2003 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each cited foreign patent document; each non-patent literature publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has not been considered.

Claim Objections

2. Claim 2 is objected to because of the following informalities: In line 6, "worth" should read as "with". Appropriate correction is required.

3. Claims 8, 20 and 29 are objected to because of the following informalities: The claims disclose the means of remote imaging detection methods and further disclose the use of visualization. Visualization is not a remote imaging detection method. Appropriate correction is required.

4. Claim 11 is objected to because of the following informalities: The claim refers to itself. Appropriate correction is required.

Claim Rejections - 35 USC § 112

5. Claims 2-14, 20 and 29 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in

the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Currently Claims 2, 8, 20 and 29 disclose the marker is "detectable by at least two remote imaging detection methods". The current specification, as well as the prior non-provisional and provisional applications fails to disclose the marker that is "detectable by at least two remote imaging detection methods". The current specification and prior non-provisional and provisional applications only disclose the marker being separately imageable using ultrasound and X-ray or mammography, but not both.

6. Claims 4, 8, 16, 20, 25, 29 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The current claims claim the use of MRI, Doppler, radiation detection, and other roentgenological imaging methods as means for remotely detecting the implanted marker. The current specification fails to disclose the use of MRI, Doppler, radiation detection, and other roentgenological imaging methods as means for remotely detecting the implanted marker. There is also no support for Doppler, radiation detection, and other roentgenological imaging methods in any of the prior non-provisional and provisional applications.

7. Claim 11 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it

pertains, or with which it is most nearly connected, to make and/or use the invention. The current specification and the prior non-provisional and provisional applications fail to disclose the clearance delaying element material.

8. Claims 13, 22 and 13 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The current specification and prior non-provisional and provisional applications fail to disclose the use of a bioabsorbable sponge. The current specification and prior non-provisional and provisional applications only support a marker that swells when it comes in contact with a fluid, which does not constitute a sponge.

9. Claims 14, 23 and 32 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The current specification and prior non-provisional and provisional applications fail to support the claimed "radiographically imageable matter attached" to the bioabsorbable mass, and only support the bioabsorbable element containing a radiopaque marker.

Claim Rejections - 35 USC § 102

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

11. Claims 2-5, 8, 9, 24-26, 29-32 are rejected under 35 U.S.C. 102(b) as being anticipated by Cragg et al (6,071,301).

Cragg et al disclose a device for facilitating hemostasis in a biopsy tract, and further disclose a mass of material that is detectable by at least two remote imaging detection methods when introduced into the cavity site from which tissue has been removed, that remains detectable at the cavity site for at least a predetermined first time period after its introduction into the cavity site and that does not interfere with imaging of tissue adjacent the cavity site during a predetermined second period of time after the first period of time; the detectable mass is imageable, and remains imageable for at least the first predetermined time period but clears sufficiently from the site so as to not interfere with imaging of tissue adjacent the site during the second predetermined time period; the detectable mass is imageable by at least one of the methods selected from the group consisting of X-ray, fluoroscopy, mammography, magnetic resonance imaging, ultrasound, Doppler, radiation detector, and combinations thereof; the detectable mass is detectable by palpation; the marker comprising bioabsorbable material, and being characterized by remaining present at the cavity site in sufficient quantity to permit detection and location of the cavity site for at least a predetermined first time period after introduction to the cavity site; the marker is detectable by

radiographic imaging; the marker comprises at least one sponge; and the marker comprises collagenous material having a radiographically imageable matter attached to the collagen. See Column 3, lines 26-29; Column 7, lines 24-28; and Column 8, lines 35-37 and 49-55.

Even though Cragg et al does not explicitly disclose the types of imaging used to image the marker, the marker comprises a contrast agent that would inherently enable the marker to be imaged by various means of imaging equipment, including x-ray, sonograms and MRI. Furthermore, the disclosed sponge would be palpable due to the different consistency of the sponge in relation to the surrounding tissue, and the differing consistency would also allow the marker to be detectable via sonograms as well as MRI.

12. Claims 15-21 and 23 are rejected under 35 U.S.C. 102(b) as being anticipated by Stinson (6,174,330 B1).

Stinson discloses a bioabsorbable marker having radiopaque constituents and further discloses the marker comprises collagen, and being characterized by remaining present at the cavity site in sufficient quantity to permit detection and location of the cavity site for at least a predetermined first time period after introduction to the cavity site; the marker is imageable by at least one of the methods selected from the group consisting of X-ray, fluoroscopy, mammography, magnetic resonance imaging, ultrasound, Doppler, radiation detector, and combinations thereof; the marker is detectable by palpation; the marker is visually detectable; the marker includes a colored substance selected from the group consisting of a dye, a colorant, colorant particles, and possible

combinations thereof; the marker is detectable by at least two remote imaging detection methods selected from the group consisting of magnetic resonance imaging (MRI), ultrasound imaging, Doppler imaging, x-ray imaging, mammography, fluoroscopy, other roentgenological imaging methods, and visualization; the marker is detectable by radiographic imaging; and the marker further comprises a radiographically imageable matter attached to the collagen. See Column 2, lines 50-65; and Column 10, lines 32-54.

Even though Stinson does not explicitly disclose the types of imaging used to image the marker, the marker comprises a contrast agent that would inherently enable the marker to be imaged by various means of imaging equipment, including x-ray, sonograms and MRI. Furthermore, the disclosed sponge would be palpable due to the different consistency of the sponge in relation to the surrounding tissue, and the differing consistency would also allow the marker to be detectable via sonograms as well as MRI. The disclosed contrast agent would also allow the marker to be "visually detectable", since it is well known in the art that contrast agents are inherently colored agents.

Claim Rejections - 35 USC § 103

13. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

14. Claims 6, 7, 27 and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cragg et al (6,071,301) as applied to claims 2 and 24 above, and further in view of Stinson (6,174,330).

Cragg et al, as discussed above, disclose a bioabsorbable device with a contrast agent, but fail to disclose the detectable mass is visually detectable; and the detectable mass includes a colored substance selected from the group consisting of a dye, a colorant, colorant particles, and possible combinations thereof.

Stinson, as discussed above, disclose a bioabsorbable radiopaque marker and further disclose the detectable mass is visually detectable; and the detectable mass includes a colored substance selected from the group consisting of a dye, a colorant, colorant particles, and possible combinations thereof. See Column 2, lines 50-65; and Column 10, lines 32-54.

Since both Cragg et al and Stinson disclose bioabsorbable radiopaque markers, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Cragg et al to allow the device to be visually detectable, as per the teachings of Stinson, since it is well known in the art that contrast agents are colored agents.

15. Claims 10-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cragg et al (6,071,301) as applied to claim 2 above, and further in view of Unger et al (6,231,834 B1).

Cragg et al, as discussed above, disclose a bioabsorbable radiopaque device, and further disclose the use of radiographic imaging to detect the mass of material, the detectable mass comprises a sponge. See Column 3, lines 26-29; Column 7, lines 24-28; and Column 8, lines 35-37 and 49-55. Cragg et al however fail to disclose a clearance delaying element to delay the clearance of a material from the cavity site; and the clearance delaying element is selected from the group consisting of polylactic acid, polyglycolic acid, an encapsulating material, collagen, and the possible combinations thereof.

Unger et al disclose a means of an ultrasound imaging means with a contrast agent, and further disclose a clearance delaying element to delay the clearance of a material from the cavity site; and the clearance delaying element is selected from the group consisting of polylactic acid, polyglycolic acid, an encapsulating material, collagen, and the possible combinations thereof. See Column 7, lines 7-39; Column 21, lines 63-67; and Column 22, lines 1-3, 40 and 47-48.

Since both Cragg et al and Unger et al disclose a bioabsorbable means for remote imaging, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Cragg et al to include the use of a clearance delaying element, as per the teachings of Unger et al, since it would provide a means of allowing the bioabsorbable element to remain at the site for a longer period of time.

16. Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Cragg et al (6,071,301) and Unger et al (6,231,834 B1) as applied to claim 10 above, and further in view of Stinson (6,174,330 B1).

Cragg et al and Unger et al, as discussed above, disclose bioabsorbable devices for imaging, but fail to disclose a collagenous material having a contrast agent attached thereto.

Stinson, as discussed above, disclose a radiopaque bioabsorbable marker and further disclose a collagenous material having a contrast agent attached thereto. See Column 2, lines 50-65; and Column 10, lines 32-54.

Since Cragg et al, Unger et al and Stinson disclose bioabsorbable devices comprising contrast agents for remote imaging, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the combination of Cragg et al and Unger et al to utilize a collagenous material with a contrast agent attached thereto, as per the teachings of Stinson, since it is well known in the art to utilize several different bioabsorbable materials including collagen, gelatin as well as bioabsorbable polymers for bioabsorbable devices.

17. Claim 1 is rejected under 35 U.S.C. 103(a) as being unpatentable over Cragg et al (6,071,301) in view of Unger et al (6,231,834 B1).

Cragg et al, as discussed above, disclose a bioabsorbable device (see Column 3, lines 26-29; Column 7, lines 24-28; and Column 8, lines 35-37 and 49-55) but fail to disclose a clearance delaying element.

Unger et al, as discussed above, disclose an ultrasound imaging marker and further disclose the use of a clearance delaying element. See Column 7, lines 7-39; Column 21, lines 63-67; and Column 22, lines 1-3, 40 and 47-48.

Since both Cragg et al and Unger et al disclose means of remotely imaging a bioabsorbable element, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Cragg et al to include the use of a clearance delaying element, as per the teachings of Unger et al, since it would provide a means of allowing the bioabsorbable element to remain at the biopsy site for a longer period of time.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Szmal whose telephone number is (571) 272-4733. The examiner can normally be reached on Monday-Friday, with second Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571) 272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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